

**NC Division of Medical Assistance
Outpatient Pharmacy
Prior Approval Criteria**

**Medicaid and Health Choice
Effective Date: April 5, 2018
Amended Date: ~~October 1, 2021~~**

Lupus Medications

Therapeutic Class Code: Z2Y, Z2E

Therapeutic Class Description: Immunosuppressive Agents; Miscellaneous; Immunomodulator, B-Lymphocyte Stim (BLYS)-Specific Inhibitor

Medication
Benlysta®
Lupkynis™
Saphnelo™

Eligible Beneficiaries

NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

NC Health Choice (NHC) beneficiaries, ages 6 through 18 years of age, shall be enrolled on the date of service to be eligible, and must meet policy coverage criteria, unless otherwise specified.

EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries under 21 Years of Age

42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiaries under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product, or procedure

- a. that is unsafe, ineffective, or experimental/investigational.
- b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a

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health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements

- a. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
- b. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *Basic Medicaid and NC Health Choice Billing Guide*, sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.

NCTracks Provider Claims and Billing Assistance Guide:

<https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html>

EPSDT provider page:

<https://medicaid.ncdhhs.gov/medicaid/get-started/find-programs-and-services-right-you/medicaid-benefit-children-and-adolescents>

Health Choice Special Provision: Exceptions to Policy Limitations for Health Choice Beneficiaries ages 6 through 18 years of age

EPSDT does not apply to NCHC beneficiaries. If a NCHC beneficiary does not meet the clinical coverage criteria within the **Outpatient Pharmacy prior approval** clinical coverage criteria, the NCHC beneficiary shall be denied services. Only services included under the Health Choice State Plan and the DMA clinical coverage policies, service definitions, or billing codes shall be covered for NCHC beneficiaries.

Criteria for Initial Coverage for Benlysta:

- Beneficiary has a diagnosis of active systemic lupus erythematosus (SLE), **AND**
- Beneficiary must be auto-antibody positive, **OR**
- Beneficiary has a diagnosis of active Lupus Nephritis, **AND**
- Beneficiary age is ≥ 18 years, **AND**
- Benlysta is prescribed by or in consultation with a rheumatologist or nephrologist **AND**
- Beneficiary must be utilizing Benlysta in combination with standard treatment regimens (NSAIDs, corticosteroids, anti-malarials, and immunosuppressive drugs) or standard treatment regimens were not tolerated or not beneficial, **AND**
- Beneficiary must not have a diagnosis of severe active central nervous system lupus, or concurrently use other biologics and/or IV cyclophosphamide. **AND**
- Maximal length of approval: 12 months

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Criteria for Renewal Coverage for Benlysta:

- There is documented improvement in functional impairment such as 1) fewer flares that required steroid treatment; 2) lower average daily oral prednisone dose; 3) improved daily function either as measured through a validated functional scale or through improved daily performance documented at clinic visits; 4) sustained improvement in laboratory measures of lupus activity.
- Maximum length of approval: 12 months

Subsequent authorizations will be granted based on current progress notes from the physician documenting disease status and clinical response.

Criteria for Initial Coverage for Lupkynis:

- Beneficiary has a diagnosis of lupus nephritis; **AND**
 - Beneficiary has International Society of Nephrology/Renal Pathology Society (ISN/RPS) biopsy-proven active Class III or IV lupus nephritis alone or in combination with Class V lupus nephritis; **AND**
 - Beneficiary has Urine protein to creatinine (UPCR) ratio ≥ 1.5 mg/mg for Class III or IV OR UPCR ≥ 2 mg/mg for Class V; **AND**
- Beneficiary age ≥ 18 years old; **AND**
- Beneficiary must not have hypersensitivity to any component of the product; **AND**
- Beneficiary must not have concomitant use of strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, clarithromycin); **AND**
- Beneficiary must not have severe hepatic impairment; **AND**
- Beneficiary must concomitantly receive background immunosuppressive therapy, with the exception of cyclophosphamide; **AND**
- Beneficiary baseline blood pressure is $< 165/105$ mm Hg; **AND**
- Beneficiary baseline estimated glomerular filtration rate (eGFR) is > 45 mL/min/1.73 m²; **AND**
- Renal function (eGFR) will be assessed at regular intervals thereafter; **AND**
- Lupkynis is prescribed by or in consultation with a rheumatologist or nephrologist

Maximal length of approval: 6 months

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Criteria for Renewal Coverage for Lupkynis:

- Patient must continue to meet the above criteria; **AND**
- Patient must have disease improvement and/or stabilization OR improvement in the slope of decline; **AND**
- Patient has not have experienced any treatment-restricting adverse effects (e.g., hypertension, neurotoxicities, hyperkalemia)

Maximal length of approval: 6 months

Criteria for Initial Coverage for Saphnelo:

- Beneficiary has a confirmed diagnosis of systemic lupus erythematosus (SLE); **AND**
- Beneficiary must be auto-antibody positive (current or past) **AND**
- Beneficiary age is $\geq$ 18 years; **AND**
- Beneficiary does not have severe active central nervous system lupus; **OR** severe active lupus nephritis; **AND**
- Saphnelo is prescribed by or in consultation with a rheumatologist or nephrologist **AND**
- Beneficiary has moderate to severe disease; **AND**
- Beneficiary has failed to respond adequately to or is unable to tolerate at least one (1) standard therapy such as anti-malarials, corticosteroids, or immunosuppressives; **AND**
- Beneficiary must not have a clinically significant active infection; **AND**
- Anifrolumab-fnia (Saphnelo) must not be used in combination with other biologic therapies, including B-cell targeted therapies (e.g., belimumab [Benlysta®]), voclosporin [Lupkynis™], or cyclophosphamide); **AND**
- Anifrolumab-fnia (Saphnelo) must be used in combination with standard therapy (e.g., anti-malarials, corticosteroids, non-steroidal anti-inflammatory drugs, immunosuppressives) or standard treatment regimens were not tolerated or not beneficial; **AND**

Maximal length of approval: 6 months

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Criteria for Renewal Coverage for Saphnelo:

- Recipient must continue to meet the above criteria; **AND**
- There is documented improvement in functional impairment compared to baseline, or sustained improvement such as 1) fewer flares that required steroid treatment; 2) lower average daily oral prednisone dose; 3) improved daily function either as measured through a validated functional scale or through improved daily performance documented at clinic visits; 4) sustained improvement in laboratory measures of lupus activity; **AND**
- Recipient is absent of unacceptable toxicity from the drug (Examples of unacceptable toxicity include the following: serious infections, malignancy, severe hypersensitivity reactions/anaphylaxis, etc.)

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References:

1. Benlysta full prescribing information. Rockville, MD: Human Genome Sciences, Inc. Updated December 2020.
2. Lupkynis [package insert]. Rockvale, MD; Aurinia; January 2021.
3. Saphnelo [package insert]. Wilmington, DE; AstraZeneca; July 2021.

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Criteria Change Log

04/05/2018	Criteria effective date
10/01/2021	Added active Lupus Nephritis as an approvable diagnosis for adults and removed Active Lupus Nephritis as an exclusion for coverage
10/01/2021	Add coverage for Lupkynis
xx/xx/xxxx	Add coverage for Saphnelo